STATE OF MARYLAND FINAL

ADVISORY COUNCIL ON PRESCRIPTION DRUG MONITORING

AMERICAN CANCER SOCIETY

WHITE MARSH HEADQUARTERS

8219 TOWN CENTER DRIVE

BALTIMORE, MARYLAND 21236

APRIL 17, 2009

9:40 a.m.

BEFORE THE HONORABLE JOHN F. FADER, II, Chairman

DAVID SHARP, Ph.D., Presenter

Director, Center for Health Information Technology

Reported by: KENDI IRWIN, CSR

ALSO IN ATTENDANCE:

DR. J. RAMSAY FARAH	LARAI FORREST, ESQUIRE
ALAN FRIEDMAN	DR. ROBERT L. LYLES, JR.
DORCAS ANN TAYLOR	DR. PETER COHEN
DR. DEVANG H. GANDHI	BRUCE KOZLOWSKI
JOSEPH PARADIS	GEORGETTE P. ZOLTANI
FRANCESCA GIBBS	MANDY DAVID
TERRY RILEY	GAIL AMALIA B. KATZ
GWENN HERMAN	PAUL HOLLY
JANET GETZEY HART	MALCOLM HERMAN

(Whereupon, the meeting of the Advisory Council commenced at 9:40 a.m.)

JUDGE FADER: Good morning. The first thing I want to do is to ask if anybody has any objections, changes, suggestions, or anything with regard to the minutes of February 27, 2009. If any of you do now, we would appreciate you talking to us about it and making suggestions. Since there are a number of people that really can't come today, we're also going to send an e-mail out and we're going to say that anyone else who has any suggestions with regard to changes to the minutes must in fact tell Georgette and communicate to her. And I'll ask Georgette to send that e-mail out today, no later than the close of business on 5/8/2009. So anybody that has anything now, can you tell us? If anybody doesn't, then Georgette will send that e-mail out.

The next thing is I'm going to ask you to take a look at your calendars. We have pretty much our last session to really gather information will be on June 5th. And Joe Curran is going to come to talk

to us just for an hour or less. You may remember General Curran was ill and could not come one session, could not come today because the lady that he is going to present this with, his son-in-law needed that lady in Annapolis, and there was no way I was going to get in a fight with his son-in-law, the Governor. I've got enough trouble in life without irritating the Governor. So Joe will be here and is looking forward to the presentation on the 5th. And then Gail and Gwenn, and who else? Just you two?

MS. KATZ: Well, we have speakers. We're going to arrange the speakers.

JUDGE FADER: You two are going to spearhead that.

MS. KATZ: That's right.

MS. HERMAN: Yes.

JUDGE FADER: That then really is our last information gathering. What will occur then is we'll send you out a great number of issues to comment on, as to here are the issues that we have seen generated, here are the categories where we feel those issues

belong, questions. And then during the summer, Georgette has a student, and a couple of University of Maryland School of Law students will start to gather all the statutes and information from other states as to what their experience will be, so that will all go along with the information as far as the issues that we need to address.

Then we'll start looking at the issues, trying to rearrange them, see who thinks what belongs where, when, how, all the adverbs and everything. And then we'll start discussing these issues at meetings and taking votes and stating positions for the Legislature. I wouldn't be surprised if there weren't two or three different positions on some of these issues, more than that maybe. And everybody will have their say. And we would ask that all those says be put in footnotes and notes so that when the Legislature gets around to this they can determine what they're going to do.

I would like to hold the next meeting on either July 10th or July 17th, and I am just going to

mention that to you now. I'll mention it to you at the end of the period, and we will all talk then about which of those days. And we'll send out an e-mail to see, I imagine with vacation periods, we'll have a little bit more difficulty with some of those days than other days and things of that sort, but we have got to do some work during the summertime. Then we have got to have another meeting in September, another meeting in October, and then a meeting the first of November. And at the end of the November meeting, then we will have maybe 45 days to write the report and get the report in. But we do plan to have meetings September, October, November, those three months in the beginning.

Anybody have any questions or suggestions or anything?

DR. LYLES: Are we going to skip the June meeting?

JUDGE FADER: No. The June meeting is June 5th. And that's the day when General Curran is going to come to make his presentation, and that is the day

that Gwenn and Gail will have speakers. And those speakers of course will be people who work with pain, and have had pain, but they will also be people who will tell you how scared they are and why they're scared of war stories that some people have gone off-the-wall and have not done well by some of the overt actions and have caused a diminution in enthusiasm for some physicians to write medicine and all things of that sort. But Gail and Gwenn know that better than I do, things that we need to have avoided.

Anything else from anybody before we start? A couple people said they needed to leave early. So I'm not sure this is going to be a very, very long meeting today, or as long as the other meetings that have gone until 12:30, but we'll see.

David Sharp works for the Maryland Health Care Commission. I have seen that name in footnotes, administrative appeals that have come before me all over the place. Their nose seems to be in so many things. And I have always said that I've got to find

out some day what they do. And Bruce is going to introduce David and also give us an overview of that small very, very powerful agency.

So, Bruce, if you would be good enough to do that, it would be very much appreciated.

MR. KOZLOWSKI: Okay, I'll be happy to.

JUDGE FADER: Bruce, you work for that agency, also?

MR. KOZLOWSKI: Yes, I sure do. The Maryland Health Care Commission is a relatively small organization that touches many parts of health care in Maryland. The first thing I'd like to do is recognize one of our newest commissioners. Dr. Lyles has joined the Commission and we're very, very pleased to have him. He should really be doing this because yesterday he was exposed to orientation and found out that in two hours we never got finished. So I'm going to keep this brief. I've asked David, which I think is appropriate, David will talk about his Center.

The Commission is divided into Centers. We have a Center that addresses the following, and some

of you may have been involved or at least heard about it. We do certificate of need. Certificate of need in Maryland is if you are going into any development or improvement for hospitals in excess of 11.2 million, for nursing homes in excess of 5.4 million, you have to come to the Commission. You go through a very thorough process in which you make applications. There is an extensive review and analysis done to see what the impact is. There is a needs analysis to see whether in fact there is a need for that to be done. And in the end, if you get approval, you get to go forward and either build or make the changes. So that affects hospitals, nursing homes.

We actually have certificate of need for home health, hospice, and med-surg or ambulatory surgery. Two of those obviously don't have brick and mortar. Maryland is unique in the fact that they deal with home health and hospice with certificate of need.

That's the operational side. On the policy side of the regulatory side is the State Health Plan.

And the State Health Plan is a rather large document that lays out all the rules and regulations that providers have to go through in order to even make their application to start with. It sets up standards, again, so that we're not wasting state resources looking at something that has no opportunity or reasonableness to even be considered to start with.

The other thing we get involved in extensively is long-term care. The agency is very proactive in making information public, so that consumers, Marylanders, can in fact look to our website, look to our reports to make conscious decisions about what they want and do not want to do.

In long-term care, I invite you all if you have pens in hand to go to www.mhcc.maryland.gov. Go to our website, there are buttons on there it will take you to various and sundry other areas. You can spend hours, and hours, and hours learning about all your business colleagues in health care in Maryland.

Long-term care is very close to my heart. I

run two Centers at the Commission, and the long-term care website actually allows you to go in and you can compare up to five nursing homes at a time and get a complete spillout of what they look like, the number of beds they have, the number of toilets they have, single rooms, what their quality of care history has been. You can actually do evaluations. That alone gets about 20,000 hits a year.

We also do an annual survey called experience of care to find out how people feel about their care in nursing hose. That has also been published, and in fact was featured nationally this year in Washington because of its success.

The other thing is we are soon to expand in that process to include assisted living, home health, hospice, and services for homes. So we're very web-based in what we do.

We also do disparities. The Department of Health does health disparities, and we do health care disparities and we deal with issues of how people are treated when they see their medical provider. That's

been our focus, and we did a briefing on it yesterday.

We also are responsible for the small group market in Maryland. Ironically Maryland is a state in which if you are an employer with 250 employees and you want to have health care and you want to do it outside of the individual market, you must buy through the small group market. And we run the small group market in Maryland. About forty percent of all the employers in Maryland participate. That sounds low, but that happens to be the national average, because others being small employers may get it through a spouse, may buy it through the individual market. So that's just another piece that we do.

And as part of the small group market, we are responsible to do the analysis, clinical, social, and financial analysis for all mandates that the Legislature opts to want to put into place in Maryland. And so we get a number of those each year that we work on. And even when we don't ask for studies, and we're strictly a fees organization, no

appropriation, we always pick up about eight or nine studies in a given year. Last year fourteen, which was kind of fascinating.

Commercial health plans. All the commercial health plans that you buy services through or participate in we oversight from a quality and performance reporting perspective. And we do that working with NCQA. We do that working with a CAPS organization and we also work with Evaluate, which is administrative review group. That is also published on our website and also provided to all State employees during open enrollment, which is occurring right now.

We have eliminated about 125,000 documents a year that used to be printed by going electronic. And we found out that the public, since we have backup for those who do not have computer capability to call in and get information with manual assistance. It's worked out very, very well, and Marylanders seem to be very, very happy with that.

We do special reports for the Legislature.

We finished a two-year report on long-term care. We also operate a partnership, which is a subsidy program for the smallest of small employers, and we are now engaged in a rather extensive effort over the next several months with the Legislature and the health plans in looking at reforming health care in Maryland and coming up with proposals for the next session.

As I said, the last piece is we have -- one of our Centers that collects encounter data from health plans, and by the year 2012, we will in fact have encounter data for all physician services and all pharmacy services. We have all hospital services. We hope from an analysis standpoint in a protected, very secure environment which we have, we'll be able to take and bring this information together and actually track and see what is occurring in Maryland's marketplace so we can better report both to Marylanders and companies about what is happening and to the Legislature from a policy perspective.

That's the short form of what an agency with 58 people does.

JUDGE FADER: Let me just say this. This is an unusual agency. The Legislature delegated to this agency, and the only other one I've had experience with that's like this is the Chesapeake Bay Critical Areas Commission, where the Legislature delegates a substantial amount of quasi-legislative functions.

The Board of Pharmacy, the Board of Physicians have the authority, very limited authority to enact regulations dealing with the practice of medicine, the practice of pharmacy. But these two agencies have enormous authority to set plans for state health care, things of that, which are not subject to judicial review. The only thing is do they conflict with the Constitution or are they within the ambit of the envelope that's created by the Legislature. It is a very, very powerful agency.

There are two opinions from the Court of Appeals that were my main introduction into the Maryland Health Care Commission. They were fighting over -- they want to put another 125 cardiac beds in some hospitals in Montgomery or Prince George's, I

can't remember what it was, and they included the Washington hospital beds. And Judge Wilner and Judge Eldridge went back and forth as to what the power of the Commission was and things of that sort. So I'll put those little things in a footnote. But a lot of what you do is legislative.

MR. KOZLOWSKI: Yes, it is.

JUDGE FADER: Most of what you do is legislative.

MR. KOZLOWSKI: It is. We're an independent agency and we are a think tank for both the Governor's office and for the Legislature, and we do it separate and distinct. It works quite well.

JUDGE FADER: What they do, they do studies, but they have as much authority probably as the Chesapeake Bay Critical Areas Commission to establish legislation outside of the Legislature. I don't really know any other agencies that have all that power, except you two.

So what is David Sharp going to do for us today?

MR. KOZLOWSKI: If we could be so kind, David is our guru in the management of data exchanges and data movement. And I have asked David to give you a brief overview of his Center and then a presentation. Do we have about an hour?

JUDGE FADER: We certainly do. Isn't the important thing is Maryland is going in to record collection?

MR. KOZLOWSKI: Absolutely.

JUDGE FADER: So that is probably the first thing. Is Ken Whitmore here?

(No response.)

JUDGE FADER: From SureScripts. I sent him all this information. He was going to come, but I have not seen him.

MR. KOZLOWSKI: David is very much of aware of all that and can talk to you about what our game plan is over the next couple years because David is also leading on behalf of the administration and the Legislature the project to go to electronic health records. Both of these work very well. I'm pleased

to present Dr. Sharp.

DR. SHARP: Good morning, everybody. It is a pleasure to be here. I want to talk to you a little bit about couple of things. I think presentations work best that are very informal. So as I'm going through, things pop to mind, if I'm taking you in a direction and not giving you enough information, stop me and let's dig a little bit. We have the time and I can assure you I won't run over. And if we can finish a little early that may be helpful to some of you.

To begin with, let me tell you about what I do at the Maryland Heath Care Commission. My job is to head up the Center for Health Information Technology. We are a small component, small center within the Maryland Health Care Commission, but we are very mighty. We do a lot of things in the industry around technology.

Two broad goals: One is to advance the adoption of electronic health records in the state, and the second one is to put into place the infrastructure to support the movement of patient

information, patient data, on this highway. Think of it in terms of the Internet, if you will, but a different form of Internet. The patient information can go from provider to provider in a secure manner where oddly enough or uniquely enough that the patient controls that data.

So what we want to do is try to put in place this infrastructure, and we're making steps to do that. To give you some examples: Today electronic health records, when you go see your physician, they're in play roughly eighteen to twenty percent of the time of the about six thousand one hundred plus physician practices in the state. So you figure that's a small number. We have a long way to go.

Today if you need your medical record you go into your physician, you fill out the paperwork, they give you the stack, in some cases a small stack, in some cases a large stack. We have wonderful patient information silos. They're paper information silos.

And for the physicians today in the hospitals that are moving into the electronic world,

that data has become more electronic. But it is still an electronic silo. Because the information is still stored uniquely to that institution.

So getting these end points to adopt the technology is very critical. It is critical for us as patients because we get better care. It doesn't take a lot of time. You will often hear patients complain about the clipboard, you go in, you have to fill out reams, and reams, and stacks of information, say the same thing over and over again. And wouldn't it be nice if that information could move around to the providers and offices that you authorize. So we are getting the infrastructure.

I've talked a little bit about the support. This infrastructure is new not only to Maryland but it is new to the nation. There has been a lot of work that's going on to try to figure out what this highway should look like that connects state to state to state. What you have are states that are building these infrastructures following some standards that have been decided upon, the policies have been decided

upon at the national level, but trying to build them uniquely enough to meet the state's needs within each individual state.

Because the policies within each of these states, the culture around how information is used, how information is handled, how information is disclosed is extremely different, Maryland versus Delaware versus West Virginia versus Pennsylvania. You would think theoretically since we are all so close to each other we could agree on how data should be exchanged. You would be amazed to know that within our own state we can hardly get hospitals to agree on how data should be exchanged. So imagine with the forty-seven acute care hospitals in the state, all agreeing a little bit, but then trying to expand that beyond state borders and then with the physicians as well. So it is a huge job.

The challenges, it is interesting to note, are not so much the technology. Most people understand computers. Most people have them. I'll bet everyone in this room is connected to the Internet

in their house and in their place of employment. It isn't a question. It is almost unheard of the other way around, to find people who don't have access to the Internet.

But when you look at it from a broad standpoint, trying to get people to agree on policy has never been an easy thing to do. Policy is really where we get hung up. Policy is predominantly around who owns the controls, who accesses our information. And that's really where some of the challenges lie.

Do you have a question, ma'am?

MS. KATZ: I just had a comment.

DR. SHARP: Sure.

MS. KATZ: I'm thinking another piece of it is getting both providers and patients to trust it, to trust it to be there. And I give you a real example from yesterday. I was accompanying a patient -- which I sometimes do, I advocate for cancer patients from time to time, to sort of understand the system -- who is in the process of getting a workup and is going to be treated at a very sophisticated cancer center in

Baltimore County. She is having a biopsy this morning and a biopsy on Monday, and had a physical in their pre-op area yesterday, all within the same building. In preparation for that they have all the MR completely electronic. They printed out four copies of her bloodwork, one for her file, one to take to the physical, one to take to each of the biopsies, which incidentally are being done in the same center. She is going to the same place twice, but they don't trust their own system to be able to pull up their own information. I thought that was extraordinary.

What it reminds me of is if you will all remember when we began to use computers, we were going to go to a paperless office. We haven't. All of us, if something is really important, you print it. Even if it is not important, you print it. I think that's an issue that we need to think about if we really, really want this program to do well.

DR. SHARP: And that's a good point. Let me play on your examples a little bit, because it creates some perspective that may be helpful. Tax day, two

days ago, we all remember that? How many of us submitted our taxes electronically?

MS. KATZ: I didn't do it, my accountant did it, but electronically.

DR. SHARP: Most of us didn't. How many will be honest and say they didn't submit it electronically? All right, maybe a few of us. It is because you don't trust. Do we trust that the information will get there? Do we trust it will be secure?

A physician here is saying no way, I don't buy any of this, it is going to end up on the Internet somewhere. Just as we heard about the president's income tax returns, we'll hear about yours, right?

It is a big issue, and you mention about the technology within hospitals. There is this notion that hospitals, that facilities that are broad that have this EMR, and I'll explain the difference between EMR and EHR. These EMRs, these wonderful longitudinal records of patient information that get stuck in this widget of technology that isn't interoperable. Nobody

shares anything with anybody because we don't trust. I know my computer, it mine I know, but I don't know what yours looks like, so I'm not going to be willing to share.

MS. KATZ: But I was talking about one cancer center, one institution that has common everything. It is one system. If I log on in the department of radiation oncology, I'm logging on to the same system that you are logging on in medical oncology. It is absolutely the same system, and they are still printing out the records for each.

DR. SHARP: It is, but if we go a little deeper into the technology, the way technology is parsed and the functionality within technology, you can have the same software, but the disparate functionalities of it are completely unique. So they don't speak to each other.

I'll give you the best case example is the chocolate chip cookie. There is only one chocolate chip cookie, but there are hundreds of ways to make it. And these are configured with the same system

computers, the McKesson system, HBOC, Siemens, they're all the same system, but they configure things differently. Your point is well put.

JUDGE FADER: Can I say as far as, Gail, I understand what you are saying, but almost everything I have is with St. Joseph's Medical Center in Towson. And I don't have that problem. When I got my bloodwork drawn two days ago for my physical, annual physical Monday, they just send that all over to my physician who is a member of that, and he takes a look at everything on line. The vascular surgeon who is in there too that treats me, that's all on line. So the systems can work because in St. Joseph there is no exchange of paper, they're all on the same system.

MS. KATZ: I agree with you. I think it is a question of training the staff and the patients to believe that and to use it.

DR. SHARP: That's a good point, because there are two components. The judge mentioned how this one hospital health system is able to be interoperable with the physicians. There are roughly

ten hospital systems within the state that are at that level of advancement, where others are still struggling because there are issues of trust. And the issues of trust are so important. I'm going to talk a little about that as we go through this morning.

JUDGE FADER: So we are making progress.

DR. SHARP: Yes, but the progress is very slow. To change culture, to change attitude, I liken it to moving the battleship in the ocean to make that turn, it is very slow. We're on the journey, but it is not one we'll get through very quickly.

So we'll chat a little bit this morning and keep asking questions. I think what it is going to do is help you as you go through to do your work, as you're thinking about what it is you are trying to produce in the end.

I'm going to bring to light in the course of the presentation really three areas. We are going to talk a little about data, how data is created, how data flows to the pharmacy. We're going to talk a little bit about the intermediaries, the networks in

the middle, how that functions, how that works, all the touch points. And then we're going to talk about the safeguarding. And you mention such a good point about trust. Because trust goes back to safeguarding. And then the three areas within the safeguarding of data that has to be looked at.

And then I went out on a limb a little bit and I said, if I were in your seats, I know I have a huge job to do to come up with some ideal recommendations. So I took from a technology perspective, so let me just be bold and throw out some things for you all to consider. I've included some recommendations for your consideration, strictly from my perspective as a technologist. And of course they'll require your infusion.

But you will find it interesting at points because I think some of this you know a little bit about, others you don't. You will take away bits and pieces that make sense to you.

So let's start with sort of a preamble, if you will, a little bit about electronic pharmacy. I'm

just going to read this to you, I know you can read it, but let me sort of step you through it and chat it for the moment.

Pharmacy data plays a key role in health care. You should know that by now. I think we have all pretty much experienced the benefits of it. Managing information and using it productively pose a continuing challenge, particularly in light of the complexity of the health care sector.

Health IT, health information technology, has the potential to significantly increase the efficiency of pharmacy data by helping providers manage that data. And we have experienced some of that in our routine life. It could also improve the quality of health care and, ultimately, the outcomes of that care for patients.

This is an interesting point. Keeping pharmacy data private and secure and identifying appropriate uses represents enormous policy challenges. And I suspect that the physician over here because of some of the concerns he has is not

willing to embark freely on just exchange of data because if on the tax side you have some concerns, you are likely to have the concerns on the health.

DR. FARAH: A quick editorial. Within the past six months we have disciplined two physicians for unauthorized access to information. We felt that that doctor or those doctors had no business getting health information, on two occasions, on two separate things that we felt we needed to discipline. So this is why this paranoia. If we have doctors that we have to discipline because of that, how am I going to be comfortable with employers, with staff, with any kind of individual reaching and doing things with these numbers.

DR. SHARP: But there is something else going on here, which you probably know, but maybe others didn't think about. How did you find that, how did you determine that there was unauthorized access to data? Probably the technology, the sophistication of technology allowed that information to be pulled out to determine that it was being misused.

JUDGE FADER: In other words, when the physicians gain entry into the system, their names or identification number was known, so the question arose as to what in the devil are you doing here?

DR. SHARP: It is a footprint.

JUDGE FADER: Is that how it happened?

DR. FARAH: In both instances that information confirmed that that person had access. I mean, he couldn't say no, I didn't. But actually in both cases were complaints from patients, how did he know, what happened?

DR. SHARP: I'll put that in perspective a little bit. That goes to the concern about trust, and a lot of this is about trust. But Johns Hopkins has a staff of people that do data auditing. They print out wherever people have been and they follow, say logistically does this make sense for the person to have been there. Software vendors have painfully manufactured products that you load into your system with defined algorithms that monitors where people go and then throws flags, should this individual be there

or not.

MR. KOZLOWSKI: David, and there is also the capacity within that software to vary authorizations, because I work with certain sets of data outside the Commission, and I have authorization to go to Level 5, where some people have authorization to go to Level 2. So there are all kinds of restrictions you can build into an operative system to minimize inappropriate access. And once you have access you do the monitoring to make sure it is being used for the right purpose.

DR. SHARP: And that's a good point my colleague brings up. A couple ways you access data, role-based access, physicians being able to access information. There is content-based, and user-based. So any user can have access once you get a log on and password to the system.

The content-based is a bit more specific that says as a user that's been approved to the system, I'm only allowed to look at information related to, say, physical therapy.

And then there is role-based. Any physician can have any access to any of this information. So there are variations within that that's important to know. These are the kinds of questions that come up from time to time. And again it all goes back to trust and that policy perspective.

So let's turn our attention a little bit more, drill down a bit, as to how the prescription data, how electronic prescribing occurs. Just to sort of paint a picture, help a little bit with some background. The prescriber initiates the e-prescribing process by sending basic information through the e-prescribing vendor to the PBM. And I'm going to show you a little bit about this.

The vendor returns patient benefits, formulary information, and then patient history to the prescriber, who then selects the appropriate drug and dosage. The prescriber then receives that drug information, allergy alerts, and then can determine, before transmitting, if any changes need to be made. It is a process, a flow that always starts and

originates and comes back to the prescribing physician to really get a handle on what it is they want to prescribe.

So the technology can be challenging, it can be difficult to understand. What I tried to do, based upon some of the feedback I received from my colleague and the judge, is to give some basic tutorial demonstrations that would help in defining how this works, clarification to build on some background we already have.

It is bi-directional. Think of it this way. Today the patients get information to the pharmacist. They skip all the technology. The physician prints it out on paper. It goes to the patient, and to the pharmacy. And that's predominantly the system we have today. But imagine how nice it would be if the patients were able to say to the pharmacist or to the physician, I go to CVS and this is the location. So the physician then prints out the prescription electronically, transmits it. Sometimes they use a fax, other times they transmit it

from a handheld product, and it goes through the channel, to the network, and ends up in the pharmacy so it is there before the patient arrives. It saves time. Also does a lot of checking in the middle, validating the patient should have that type of information, it does some insurance checking. So there is a lot of activity that goes on in the middle before it gets to the pharmacy. You can see the processing arrows both ways. It is a complex process.

Any have you ever been to see a physician who was e-prescribing?

MS. HERMAN: I just went to one. It was wonderful.

DR. SHARP: Was it? By the time you got to the pharmacist it was all there?

MS. HERMAN: It was all there, yes.

DR. SHARP: How about for physicians, anybody doing e-prescribing today? How do you like that, Dr. Lyles?

DR. LYLES: Well, except for Schedule II.

You have difficulty with Schedule II. What I have to do, I can send Schedule II with the software I have. The new software I can't do that anymore, they locked it out. But my software is a little older. So I can send Schedule II, but the patient has to take the original prescription and match it up, when he arrives at the pharmacy, before it is filled.

JUDGE FADER: The DEA is considering -- the Attorney General is considering regulations now that would provide a system for communication. I don't know how far along they are and whether the gentleman from DEA knows, but on their website they are considering electronic transfers for Schedule II. What that means --

DR. FARAH: I think the sophistication for successful outcome there would be at the pharmacy management system. I think that's where you are going to have a lot of regulations.

DR. SHARP: Right here.

DR. FARAH: I deal with the pharmacy management system area. Number 3. I think that's

where the filter is going to have to be to verify the validity, dosage, authorization, all the problems that go in with this.

DR. SHARP: Well, that's an interesting point because the validation in the technology world is built into all three layers. It depends on each of the three layers, how it is interpreted and the product. You mentioned you had yours for a while. It is an older product?

DR. LYLES: I've had it for about three years. But the newer version, I haven't upgraded it because they did lock out the Schedule II portion so you can't fax it or send it electronically.

DR. SHARP: It is interesting what constitutes electronic. There is electronic where it goes from one machine, the handheld of the physician, to the pharmacy system, shows up on the screen for the pharmacists in the back of the room to fill the order. That's a computable, interpretable prescription. That's utopia.

There are flows that the physician sends the

prescription and then it arrives via fax. They were concerned about the fax, because you are talking about the integrity, the security of it. It is not a concern to be Symantec, that is where that information is completely secure in a system that has the appropriate safeguards, where human intervention -- there would not be anybody who is touching the data. If you have somebody who is printing it out as a fax, it raises questions, because at that point it can be altered, it can be manipulated. It is not a question of am I able to read the prescription, but you get a lot of times from pharmacists on the paper version, it is indeed, is this what was requested by the physician.

MR. KOZLOWSKI: Is that the same if you have electronic fax?

DR. SHARP: Yes.

MR. KOZLOWSKI: Still the same problem?

DR. SHARP: In theory somebody at the pharmacist side could manipulate that fax.

JUDGE FADER: There is also an issue, I have

expressed displeasure with the Board of Pharmacy for not clearing this up many times. There is no such thing in Maryland as the acceptance of an electronic signature unless both parties are contract parties under the electronic signature act to that. In other words, when Dr. Lyles sends his prescription, that pharmacist in order to legally accept his signature must be a signatory to that contract. A lot of pharmacists don't know that, and the Board of Pharmacy sloughs it off on their website, and doesn't say that with the provision. A lot of prescriptions are being filled, but unless the pharmacist is a signator, it is not under the state system accepted, and a lot of pharmacies don't realize that.

DR. SHARP: Good point. Yes, ma'am?

MS. KATZ: Inpatient prescribing is very, very smooth. Assuming it is an electronic medical record for an inpatient -- actually for an outpatient as well, if the patient goes in for chemotherapy, and all of the prescribing, and the testing, and the whatever happens with no paper. Is there something

there to be modeled on?

DR. SHARP: Let's talk about that for a moment. It is a great question. It is important to know before you ponder that question, that inpatient pharmacy today is unique. It operates on what is called CPOE.

JUDGE FADER: Can you tell us the definition of inpatient pharmacy just for people when they are reading this?

MS. KATZ: The patient is in a bed and the doctor comes in and changes their prescription, and the prescription is entered electronically. It goes to the pharmacy, where it appears as a work order. It also appears on the patient's chart. It goes to the insurance company, it goes into the billing system, it goes into probably inventory. We're going to use this now so we need to replace it, and it is only touched once by the physician. It is challenged by the system in case the doctor has made some sort of --

JUDGE FADER: It is called a medical order.

MS. KATZ: Exactly. And one of the

advantages to it is it is only touched once. It doesn't have to be recopied and reinterpreted so the error rate is reduced.

JUDGE FADER: But the patient is in that nursing home, in that institution.

MS. KATZ: Could be in their outpatient facility as well, but within the institution.

JUDGE FADER: And there is a pharmacist who has a contract with that nursing home, who is part of that system?

MS. KATZ: I don't know about nursing homes.

DR. SHARP: No, no, no. Let me back you up a little bit.

JUDGE FADER: Long-term care facilities.

MS. KATZ: I'm talking about your experience at St. Joe. A prescription is written and it flows down to the pharmacy, it is filled, you can pick it up, or it is delivered to you because you are in a bed. I hope not. But it is delivered to your nurse who knows --

JUDGE FADER: That's what they refer to as a

medical order.

DR. SHARP: That occurs within inpatient settings, through a system called computerized physician order entry. Health information management systems and hospitals all have that capability. It is seamless, it works nice. That model is unique because the universe is contained. It is contained through one system. And you are talking about the use of a system. It is secure, the process is set up, it flows nicely.

For hospitals to prescribe to community pharmacies, we did a survey of the forty-seven acute care hospitals about five months ago to explore how much e-prescribing is occurring from the hospital setting to the community pharmacist. And it is very small. It is less than five percent because the technology is not there because the infrastructure is not there to support it.

If you recall, one of the things I started out speaking about is that we're trying to put into place this infrastructure to support this sort of

prescribing and flow of health information. Hospitals that have that capability have created their own model, have been able to hook up to a unique set of pharmacists. It isn't widespread, it is usually pharmacies that are connected within the service area.

So it is very limited, but it is a secure model. Any time you have a closed system you have a different kind of model, and you can define the security you want to have in play.

So this is sort of an easy way of saying how does patient information move on the prescription side once the process is in place. Again, many people think that if you don't like computers this is the best way. But if you are interested in technology, this is the best way. But again technology doesn't always make our lives easier. In fact, it complicates it a bit in many ways. I'll talk a little bit about that, but I wanted to plant that seed.

This is another perspective. Starting over to your left of the one too many scenario, where a

prescription can go many different ways. Let me sort of explain. It starts here, as Dr. Lyles mentioned, from his writing a prescription from some sort of tablet, handheld device. It travels to a broad network. That network does a lot of things with the data. It validates it, it authenticates it, it does some matching to make sure the information is appropriate to the patient.

And then depending upon how that's set up and who the information goes to, and how that provider is set up, that information can go direct to the pharmacy, it can go direct to a pharmacy hub. These are called networks.

And I'll talk to you a little bit about that in the network component. There are roughly ten of them in the state that are acting pharmacy hubs. And that hub can send it to what is called a value added network, a VAN. These guys typically read the data that's being sent from here to here. They actually look at it, they say is this data correct, does it meet certain parameters. They are inspecting the

data. If there are problems with the data they go back to these guys. And these guys send it back to the prescriber. So it is a flow.

If it goes from here to here and then down to this point, the value added network. The value added network is like a postman, never opens the envelope, he just sticks it in the box. If the process, the contractual relationship is set up between the system, this point, and to here, this is your mailman, this guy just delivers the prescription. It happens in a click of a finger that this whole maze encounters. If it goes to the value added network, they push it out to either a fax, as we were talking about, they push it out electronically to a pharmacy, or they push it back to the value added network, the pharmacy hub, because the delivery end points aren't correct. The value added networks are starting to go away. In the world of technology you want more sophistication, and that's the hubs who read the data, to make sure it is what it is supposed to be. A very complex maze.

It is interesting because you think, well, gee, why is health care this complicated. If I might borrow your phone, it happens the same way with this. Every one of us in this room again, I'll bet, has one or as my colleague has many. And when you make a phone call it works just the same way. It travels through this intricacy of technology before it gets to the end point. So you start from your cell phone, to colleagues, friends, and it travels through a network of communication hubs, pretty much similar to what is shown here.

JUDGE FADER: Can I ask you right here to keep in the back of your mind encryption and secured networks that we can talk about later?

DR. SHARP: Sure. And let me just tell you a little bit about how that works today. When you send data, you as the physician, when you are sending it through this process, it is all protected, it is secure. These networks are secure networks. If you ever look on your computer and you are entering a website, you see a little computer at the bottom with

a lock on it, it is saying it is a secure network. That means the infrastructure is in play, it has the safeguards built in to protect, ordinarily. There is nothing -- technologists will tell you there is nothing that is a hundred percent secure. You are dealing in minutiae, whether it's 99.999 or 99.8, but there is security protection built in because it is a secure network.

JUDGE FADER: Does that mean that anyone who intercepts that communication can't decipher it?

DR. SHARP: The average person cannot decipher it. The average person cannot decipher the data. But again we go back to the caveat, there is no such thing as data that can't be accessed or interpreted.

JUDGE FADER: There are so many people in the Baltimore County Detention Center now that are there just because --

DR. SHARP: They did the wrong thing.

JUDGE FADER: No. They just were smart enough, and that of course was a problem that we all

have and need to talk to you about.

DR. SHARP: Some people say if you spend time -- I guess it is an interesting policy question. Do you spend time building technology that the encryption is so secure that it keeps going up, and up, and up in the levels, or do you keep strengthening the laws that makes it less attractive to want to hack into the information. I guess to the attorneys in the room, it is probably an interesting debate.

JUDGE FADER: If there is money in it to be made, people are going to try to take advantage of injecting themselves into the system to make money.

DR. SHARP: That's a very good point.

JUDGE FADER: Do you have a lot of that down in Baltimore City, any prosecutions with regard to anything yet in computer invasion, anything, or is that pretty much the Attorney General's job?

MS. FORREST: I really don't know. I haven't had any of it, but I do narcotics, so I don't know. My knowledge is limited.

JUDGE FADER: This is a big, big concern to

everyone in this room as to the people who know how to get into these systems and what that is going to mean for the patients down the road and the privacy.

DR. SHARP: Yes. The networks are secure. The encryption, the security protections are well above industry standards. When we are looking at building the infrastructure, we're actually looking at people to go well beyond industry standards when it comes to what is acceptable, what you would have on your cable and your satellite TV, the encryption of those signals, to us, is insufficient when it comes to the data. They are here. We expect it to be way up here.

MR. KOZLOWSKI: David, talk for a couple of minutes about the fact even encrypted data moving from Point A to Point B, there are anti-hacker mechanisms, both human and technological, that are monitoring to see if anything is being intercept at any of those points in time.

DR. SHARP: That's a good point Bruce mentions. These pipelines are pretty solid. I mean,

they're virtual, but they're solid. So when there is intrusion to try to get into these, the technology will send flags that say, look, there is something going on, something inappropriate. So there are technology flares, if you will.

But I will caution, again, it goes back to is there really any way, if somebody has their heart and mind set on doing this and has the right know-how, and the right tools, and the right people, is there any way you can protect it? And the answer to that is not really. But the protections are there.

I would argue if we go back just to point out, we live with that today. If you didn't have this layer here -- we live with those same concerns from here, to here, to here. It is paper. And physician's offices, pharmacies get broken into all the time. You mentioned you prosecute narcotics. Is this sometimes people breaking into pharmacies or doctor's office to get drugs?

MS. FORREST: No. It is more stealing prescription pads and writing their own prescriptions

and things like that.

DR. SHARP: Interesting. But in cases where the actual facility has been entered, unlawfully accessed, your medical records are available. Oddly enough, what about the cleaning people? I don't know if your office uses an outside service or not that comes in at night and cleans your office. I always -- you know, when HIPAA was first introduced, it had certain requirements around the physical environment, patient information and how it is protected. It says essentially it is supposed to be secure within a secure location. And many providers, many pharmacists would assert different logic around how to protect it. The notion and the fear is if the chart is laying out on the physician's desk, or the prescription once it has been filled is laying around at night, and you have somebody come in to clean, or maybe have a maintenance crew, or you just have maybe consumers that have access to the facility, they could still easily pick up that information.

So really is the paper world all that much

more secure than the technology world? Many would say the paper world, if we are concerned, we should be concerned about the paper because that's really where the risks are today. The technology has risks, but no where near what we have been living with today. I just wanted to share with you and create some perspective when you think about technology.

So this chart when my colleague looked at it yesterday, went, oh my gosh, that's going to require some explaining because it is so confusing. And what I did -- anybody in the room from SureScripts?

JUDGE FADER: Ken did not come up. I sent him all the data on Monday, and I don't know what happened. But they'll get a copy of the transcript of your presentation.

DR. SHARP: This is interesting. What I did, SureScripts and Rx Hub are pharmacy vendors that in the past were staunch competitors, though they did it a little differently. They moved pharmacy data. One did more validating with PBMs. The other moved data to pharmacies. They merged in the fall. But for

purposes of this presentation, I'm going to split them out to show you the differences in what they do and how that data moves.

So we start here with the physician prescriber, and let's follow to your right for a moment just so you see the flow of pharmacy data. This is how the intermediaries work. Remember the intermediaries are the guys in the middle. It starts here, becomes a prescription. It goes to one of the vendors, the intermediaries that sits in the middle. They move the data to SureScripts. So now they are handing it off to somebody else, who then sends it to the pharmacy and the pharmacy then checks eligibility. Because the pharmacist will tell you they actually determine eligibility on the pharmacy at the time they receive it. Unlike hospitals, who determine before we come there for services if we have insurance or physicians who often times send the bill only to find out that there isn't a third-party payor. That happens very quickly.

So once that is carried on, it goes back to

the middle guy, on to the PBM, and once it is approved, it goes back to through the same process. But where the prescription is filled, here in the middle, and the patient can pick it up at the pharmacy. That's one dynamic where SureScripts is predominantly the network that moves that data.

On the other side of the equation we have Rx Hub who does the validating for the PBMs of the prescription, of the coverage, of the dosage, the medical history of that prescription, how much has that patient received or has been filled. From a prescription drug monitoring program, where there is a third-party payor, and most of the offenders don't have insurance when they're doing that, obviously, but there is some value because when you travel up this way, same sort of process, it goes from here, down to the PBM, from there it can either ricochet through another network to the pharmacy, but usually the process sends it back through the chain. And then it goes back. Once it gets to this side, it then goes to this side. All this in less than a second. That's a

lot of touch points in the middle, lots of touch points.

So I thought it was worth showing you so you can get to see how the people in the middle sit. And as I was telling you from the prior slide, when you have SureScripts, you can put other layers in the middle, they are sending it to different networks. It's complex. That's probably the biggest message. It may look convoluted, but it is complex. I think that's what you want to hang on to.

With the idea of people in the middle, there are policy decisions that have to be made. So what I wanted to sort of show you is how data flows, how the pharmacy transactions move, and where the policy points are. You will see different policy points here and here.

Let me explain that for a moment. So when the physician sends nonstandard, that's data that's not configured in a certain way, and why is that important? Because if it is not configured in a certain way you add layers to it, you add more

networks in the middle. When you add more networks, you add more cost, more risk for things to happen to the data.

So obviously nonstandard transactions are not where you want to be. These guys have to convert it to standard, NCPD 5.0. I don't know if you're on 5.1 or 5.0, but I still think it's 5.0, and then on to the payor or wherever the end point of the transaction happens to be. Policy decisions have to be made here that requires the physicians, when they are working with their networks, their vendors, to work through these policy decisions about security, confidentiality, often times can be false, often times can be uses and disclosure of the data. But it still has to occur.

In this scenario, you are taking standard transactions and you are converting it to a nonstandard transaction. See up here we start at nonstandard, went to standard, and here went standard to nonstandard. There are differences in technology. So if your end points aren't using standard

technology, you don't start out using standard, there is that conversion confusion in the middle.

The bottom shows where there is nonstandard to nonstandard. This is in some ways the worst configuration because no one has anything. It is disparate systems, if you will. It is important to think about because there are lots of policy debates that can go on in between. I wanted to give you an idea. With that comes charge points.

I will talk briefly, I won't get into them in detail, but somebody is paying. This transaction is not moving free. Either the pharmacist pays -- and I believe the pharmacists will tell you, there is a cost every time they get an electronic prescription. So if we say electronic prescribing is required, you have the physicians who are buying the software and paying for the use on their side. Then you have the pharmacists who are paying to get that transaction electronically. Some pharmacists will say why are we shouldering the costs? Some physicians will say how come I got to buy the technology? And in the middle

the consumer benefits, but yet there are costs on both sides.

Any of these yellow boxes in the middle where there is the Rx Hub or SureScripts or anybody who touches it in the middle, there is a charge attached to it. It is a very small charge. Even if you are talking as little as a penny or ten cents, we are talking millions and millions of transactions, you can do the math and see where it takes you to, particularly if you are paying on one side or the other.

MS. KATZ: But does it build in an efficiency? Is there also a savings at the pharmacy and/or the doctor's office?

DR. SHARP: I am so glad you asked that question. It opens the envelope on another full series of debates. But let me just answer that question. The savings isn't to the people that necessarily -- the savings is to the system and not necessarily to the end points.

So for the pharmacist there are savings for

them if they can find efficiencies by implementing that technology. Mostly pharmacies are very efficient anyway and seldom do you ever walk into a pharmacy and think this place is really chaotic. You very seldom see that. So the efficiency goes to the health care system. But for the pharmacist or the physician who has to shoulder the burden of the cost to implement that, they are not going to see any savings necessarily on their end.

On electronic health records on an infrastructure for exchanging health information, once you create efficiencies for the systems, they do flow to the end points, but not initially. It is like somebody has to make the initial investment. It does get there, it just takes time. That is a very good question.

I can tell you more about some of the efficiencies in a few minutes when we get there. Yes, sir?

MR. FRIEDMAN: I understand the intermediaries and the discussion is complex. I want

to understand the basic difference between the SureScripts network and Rx Hub. Is SureScripts primarily benefit eligibility, and Rx Hub is claim, or that's not really true?

DR. SHARP: That's a good question. Let me back up a moment. Remember up until the end of last year, SureScripts and Rx Hub were on opposite sides. They are now together. They are one organization. What happened was you're right in line with how it works.

The SureScripts component was the network that delivered the transaction to the pharmacy. They were taking it from the application that Dr. Lyles has in his office and moving that data to the pharmacy, to the CVS, the Rite Aids.

Rx Hub was taking the information from the device, from the application that Dr. Lyles has in his office, and they were running it back to the PBM to determine not only eligibility, but looking at how the prescription has been filled, the past history, looking at generic versus brand, looking at cost to

the consumer, the best drugs to prescribe. It also provides some alerts, some warnings, and so forth.

But one depends upon the other. More Rx Hub depended upon SureScripts, because once Rx Hub said here you go, here is information about the prescription, it bounced back to the handheld device Dr. Lyles has, then he is going to hit okay, got it, send. Once he hits send, it is going to go back to the SureScripts component and get to the CVS.

JUDGE FADER: Can we talk about the third system, which is Medicaid? The pharmacist wants to find out whether this prescription written is going to be paid for. They can do that immediately through the state system.

DR. SHARP: Today they can do that, but it is actually using a different system.

JUDGE FADER: Different than SureScripts and Rx Hub?

DR. SHARP: That's correct.

JUDGE FADER: It is a very efficient system.

DR. SHARP: Yes, but in the future, once

this infrastructure is in place, all these systems will eventually be enveloped into one.

JUDGE FADER: You wish. You hope. We fear.

MR. KOZLOWSKI: That's my job.

DR. SHARP: If I go real slow, and I'm forty-seven, I can retire in --

JUDGE FADER: But the situation is we don't want to get lost in all that shuffle, and that's something that's primarily -- the system that's used by Medicaid, is that pretty standard all across the United States?

MR. KOZLOWSKI: No, sir. And I can talk to that because I was the Medicaid director for a number of years. There are several vendors in the country. There is more standardization today in what is required, but how you operate hasn't been standardized. So some states operate in systems that are significantly more efficient and sophisticated than others. They don't upgrade on a standardized basis. You have a lot of legacy systems operating out there that should have been replaced a long time ago

and as a result things move through that should not move through. And a good editing system you can have a relatively free error environment from fraud just by setting up appropriate edits. But a lot of these systems that are aged just don't have those capabilities.

JUDGE FADER: So the federal government, that is paying most of these funds, has still not been able to mandate to the various states that they get in line with regard to these prescribing systems?

MR. KOZLOWSKI: There is an awful lot of politics by the vendors who run these systems at about fifteen to twenty million dollars a year for that not to happen.

DR. SHARP: It is moving in that direction, but as Bruce mentioned, it is very slow. This systems can be very functional, but they're very narrow. Eligibility requirement is not electronic prescribing. If you want to create value, you have to have it so that you are not using one system, and then with another system, and another system.

JUDGE FADER: Ann, does the Board of Pharmacy ever receive complaints from citizens, or pharmacists, or anyone about any of these three systems, Medicaid, SureScripts, Rx Hub, anything?

MS. TAYLOR: Our complaints, we don't get complaints necessarily, but we may get practice questions and concerns.

JUDGE FADER: Practice questions. Okay. So the system pretty much is working well enough to keep complaints coming through the Board of Pharmacy.

DR. SHARP: But the system is not efficient.

MS. TAYLOR: I don't know if it is that it's working or it is the knowledge of the users that maybe they're asking other people about the system or their concerns inhouse. I don't know that there are no complaints and so we are not getting them, or if it is going to another place.

DR. SHARP: Let's travel on. The questions are good. So hopefully this is creating some thought process in your mind about how to interpret all this. Let's talk about interpreting the data. Let's talk

about specifically to computable pharmacy data and what the role of the network is. By now you sort of understand the intermediary, the guys in the middle. These are networks.

In the one slide you saw a little bit about moving standard to nonstandard. In support -- and I want to go back to the scenario of the chocolate chip cookie that I used early on. It is important to keep that in mind when you think about standard.

Folks go, well, once you have the standard, the standard is the standard and it should be fine. But every vendor who manufactures a product has a standard. It is standard that they have when producing the product, but it doesn't mean it communicates with another system. There is one chocolate chip cookie and multiple ways of making it.

And that's what you have in health care, health data. There are so many different standards. There are standards that are approved standards, but still won't communicate. And there are versions within the standards. Very important.

I'll give you an example: For health care data -- it is called HL7, Health Level 7, the data flow, and within that standard they have different versions. And if you happen to be using a different version from the colleague sitting next to you, you can't share that information electronically.

So there are challenges around versioning of standards. So it is important to know that in the end Maryland has roughly ten networks, ten pharmacy networks. We have forty-two networks that can carry administrative transactions, but only ten of those forty-two can carry pharmacy transactions because of the sophistication that's required for the pharmacy data. So that is unique to what's here in the state. Yes, sir?

MR. FRIEDMAN: Is MCPDP a standard?

DR. SHARP: It is a standard. There are lots of standards, but that's the one primarily for the pharmacy. Although they use EBXML as a standard, they use NZX12 as a standard. But these standards, they can't do this. They don't communicate.

MR. FRIEDMAN: But most pharmacies use MCPDP.

DR. SHARP: This is just important to know about the variations in the standards. I just want to show you this one last slide about how they communicate. Pharmacies achieve compliance by using translator services. Whenever we talk about standards, whenever we talk about translation software, it's something that sits in the middle. When you have translation software, it always adds costs and risks, even though they're very protected and even though they can be secure, it still adds dimension to it that is important to note.

And then of course you get to the bigger network. What we are trying to do in Maryland is eliminate all these translation services and reduce the number of networks. If you think about it, what we said we wanted to put in place is a health information exchange, that is one network, one pipeline, that once you access, once you get on -- perfect example, when you get on 695, you can get

anywhere you want around Baltimore City ideally or in theory. I'm not so sure how fast. You use that as the predominant way of getting around the system. That is sort of the infrastructure for health information technology, one infrastructure.

So they eliminate -- as the judge mentioned, you have the Medicaid system that does really well with pharmacy data, you have MCPDP as a standard within that, and then you have Rx Hub and SureScripts. We get to pull everything together and make one out of that infrastructure.

I'll jump, we talked about it a little bit in other ways, but it is moving data and having conversion points, our conversion point to get the data to the PBMs, and that is indeed always a challenge, is making the data accessible very easily.

Let me tell you before we jump into the safeguarding information about today's environment, just nationally for a moment, something to think about. More than 3.52 billion prescriptions are written annually. Thirty-five million of that billion

are sent electronically.

Prescription medications are used by fifty-nine percent of the under sixty-five population. Eighty percent of the over sixty-five population.

Pharmacy staffs make more than 150 million calls today to physician practices to clarify prescriptions. You talk about efficiency. There is your efficiency. Imagine if you didn't have to do that.

Roughly 150 technology vendors are certified to transmit electronically to pharmacies. Dr. Lyles if he's shopping around the vendors and he wants to replace the system, or other physicians in the room, you can indeed shop the market. So if you like a competitive market where you have choices, it is there.

In terms of pharmacy software, the vast majority of chains use certified software; roughly seventy percent or about 42,000 pharmacies support e-prescribing. Let me just say something about

certification real quick. Today there are national organizations that certify systems, that certify to make sure there are a core set of standards around functionality, security, and interoperability. There are these groups that have been recognized to ensure that you are minimizing some of the configurating challenges that occur early on.

JUDGE FADER: Are they government systems, or are they like Good Housekeeping or something from the outside?

DR. SHARP: That's a good question. The large one that I'm referring to today is called CCHIT It's the Certification Commission for Health Information Technology that was funded by the federal government under the prior administration. It obtained its seed funding from the Office of National Coordinator under HHS. It is supposed to be self-sustaining within five years. It is well on its way.

JUDGE FADER: But it is supposed to be a private group?

DR. SHARP: It is a private group.

JUDGE FADER: Private standard group.

DR. SHARP: Correct. So that organization does the certifying. There is good and bad about certification. Because what happens is when you certify systems, it is not cheap. It is almost as though you can end up pushing the little guys out of the market. And some of the concerns that were raised by the smaller vendors is how does somebody get into the market if you have to already have something that is sophisticated and in use and in play, where do you get the money and how do you get the resources to get it tested and get it out in the field.

So there are some arguments about the haves and the have nots when it comes to certification. That is going to be a challenge going forward. There is no easy solution for that.

Let me take about -- do I have about fifteen more minutes?

JUDGE FADER: You keep rolling. We are fine.

DR. SHARP: I'm not putting anybody to sleep. Do you have a question?

DR. COHEN: I'll save it to the end, and I promise to let you know when I fall asleep.

DR. SHARP: Somebody elbow him. There are really three ways of safeguarding that I want to tell you briefly about. There is administrative, there is physical, and technical safeguarding. When you think about data, think about prescription data, let's think of how we can do that. Anybody who is moving data, there is a minimum set of standards that go into play to protect that information. I just want to show you the lay version. Because if we really expanded each one of these out, it would really put you to sleep if you're not interested in this stuff.

I want to talk to you about some of the protections that are already in play to sort of address concerns about information being accessible by other people, being hacked someplace along the line. Administratively, policies and procedures are required to prevent, detect, contain, and correct security

violations. So one of the comments that Bruce made earlier on was he said that data and flow, there are systems that sort of send out the red flares if it is being hacked into. This is one of the requirements that are core to any sort of technology system.

There has to be a security official, somebody who can stand back and say we're watching what is going on, we are making sure that when this information moves it is protected, it is secured, it isn't just a free for all. I routinely laugh and say that these are the great kinds of jobs to have because you get to watch and see what is going on. And they are also very high paying jobs.

Policies and procedures are required to ensure appropriate access to electronic data. This goes back to how do you define who has access to it, how do you grant authorization, what are the parameters around it, what makes -- what entitles me to have more access than you or than you to the data. So you have to have policies that define that and they have to be fairly consistent.

Security awareness training. When data moves people need to understand what it means, how it is protected, and the risk. So everybody is involved in how information is to be accessed and maintained. Policies are required to address security incidents. If something happens to the data en route, what do you do, who do you notify? Do you notify the physician, do you notify the pharmacist, notify the consumer? Who gets notified? Or is it the networks who get notified?

Policies and procedures are required for addressing emergency occurrences, what happens if there is a fire, if something happens to these networks. Remember, these networks sit out here. There are a number of networks in Baltimore. I know one of them resides in an old school in the city of Baltimore. You wouldn't know it was a network driving by it, but that information is protected. If you go into the building, the fire extinguisher system is so unique that if a fire occurs, it sucks the air out of the room immediately. It puts out the fire. There

are no chemicals, sprays. It just draws the air out immediately. It's very impressive how this technology is protected.

MR. KOZLOWSKI: Unless you are the analyst in the room at the time.

DR. SHARP: You may want to get out quickly, right. Periodic technical and non-technical evaluations are required to make sure what you have in place is appropriate and to be able to look ahead and see what kinds of changes that need to be made.

The whole notion of business associates, I think we have a couple of attorneys in the room. Yes, we have a couple of attorneys. In reviewing the relationships with entities that are trading health information, they strike out these deals, these business associate agreements, how can information be used, how does it work, how lawyers get involved, judges often look at it to say is this correct, or is it not when there are challenges.

But this is where the policy end of it comes in, too. If you recall, way back earlier I showed you

a slide and said, business associate, business associate. These are where some of the policy decisions are made which eventually become contractual. But they are very important because you can have one or many business associates when it comes to health information.

JUDGE FADER: Let me just put something here, too. We are not the only group that's interested in safeguarding this. There are many consumer groups, many unions that are interested in making sure that this data for health is safe. They don't want businesses using this data to determine employment. Anyone else? The unions I know are in on it, a lot of consumer groups. Anyone else that you can think of, too, that are at your heels all the time about this?

DR. SHARP: Oh, my gosh, I could talk hours about the concerns of the groups that are out there.

JUDGE FADER: Are they primarily the unions and primarily --

DR. SHARP: ACLU.

JUDGE FADER: -- consumer groups, ACLU?

DR. SHARP: All consumer groups. Any consumer groups interested. Because as you mentioned, Judge, imagine if employment, your employment becomes at risk because your employer has information about you. Think about how horrible that would be, if that were to occur. These are issues that we grapple with around electronic health information all the time.

JUDGE FADER: Maryland's Law School with its health law program received an awful lot of input with regard to genetic testing. And many legislatures have enacted laws prohibiting the use of that. So we are not the only ones who are going to be alone with regard to all of this. There are all sorts of people coming out of the woodwork who are going to be on board for the protection of the data.

DR. SHARP: I think if most people, not just Marylanders, but most people in this country knew how much data that a number of employers already have about us as employees, it would be frightening because that information is there. It is often times used

because it is pieced together not necessarily from one file, but from many different sources. And it is frightening.

JUDGE FADER: And a lot of which they're not supposed to have.

MR. KOZLOWSKI: There are two large data banks -- I think there are two at this point in the country where all claims for health, auto, life, you name it, go into those data banks. When you talk about security, those are national repositories, and you could have a hey day there.

JUDGE FADER: They're independent groups, they are not government groups?

MR. KOZLOWSKI: They are not government, they are independent groups.

JUDGE FADER: Boy, I've been in some trials and some experts testifying and they pull the deposition out and say isn't it true that in Toronto you said just the opposite and things of this sort. Another question is who has access to all of that.

DR. SHARP: Well, there is another piece,

I'll just interject it here, it can take us down a different road. Data that's shared and flows, there's anonymized and the identified. You might ask, what is the difference?

The identified data that moves that say your employers get some information as they do their health insurance evaluation for the underwriting purpose, that's data that the insurance companies, they encrypt if you will. They take out the identifiers of you and me so nobody knows on the other end who it is. But if it is fed back to the insurance company, they can retag it with our names so they know who it happens to be. So there is a key to it if you will.

The anonymized data, it is stripped. The source of which strips it, they lose the key. And as it travels through the system where it ends up at an employer or even if it were to be intercepted by somebody it is not usable because it can't take it back to me as the individual.

So there are two different ways of protecting the data. We could talk a lot about it,

but perhaps at another time.

Let's talk about the physical safeguards, moving onward. Policies and procedures are required to limit physical access to information systems and the facilities in which the information is housed. So the school downtown in Baltimore City if you found out it wasn't a school, it is a data warehouse, what is it that protects me from getting in. And once I'm in that system, let's say I'm an authorized user to have access, how am I restricted in my ability to use it has to be defined.

Policies and procedures are required to specify the proper functions that can be performed and the manner in which they can be performed by those authorized users. Because let's say I can get into the system. How much information should I have at my fingertips? How much should I have access to?

Policies and procedures that detail safeguards on all work stations. Once you get access to a work station it isn't necessarily the key to the network of information. It should not be.

Policies and procedures are required that govern the receipt and removal of hardware and electronic data from the institution or organization.

Let's talk a little bit more about technical safeguards. These are policies and procedures required for electronic information systems that maintain data to allow access to only those persons or software programs that have been granted access rights. It gets back to what I talked about role-based access, user-based, content-based.

Hardware and software mechanisms that are required that record and examine information that contains data use. This is also a way of tracking, this is the footprint we spoke about earlier on, to make sure we record who people are. And blockers for improper alteration or destruction is another component of the technical safeguards.

And lastly on the technical safeguards, policies and procedures are required to verify that a person or entity seeking access to data is the one claimed. So when these networks move data, as they

enter into each other's network, they are authenticating, how do we know the network is who they say they are. They go through a series of authentication steps.

Policies and procedures are required that guard against unauthorized access to transmitted data. Again, we get back to the concerns that Bruce made, but from a different angle about information in the pipeline, how is it protected.

So what I wanted to do as I sort of wind down in the last five minutes is just say basically I know a little bit about what you all are trying to do in conversations with the judge and my colleague, and I had a chance to attend a breakfast work group meeting recently in a small group. I say I think I hear what is going on. I understand what is going on in the industry around prescription drug monitoring and the programs that are out there. What can I offer you all as some provocative ways to think about what you want to do moving forward.

I came up with some elements for

consideration in terms of approach. I have four of them here. I have touched upon them indirectly, but let me just share them with you as we wind down.

The first one is one way you can do this is require pharmacies to submit data directly to a third party vendor using a defined data structure which would be the standard, used physical media, transmitted over the Internet or use hard copy medium. So you could say some limited data elements for prescription drug monitoring we want to send to a third party who will do the analysis for us.

The next one I thought might give you all something to chew on is you can ask existing pharmacists to use their systems in place to extract specified data and to submit that data through the current infrastructure of the pharmacy networks. If you recall I showed you this full array of networks and how they work. You could go in and say, look, we want these data points and this information, and we want it to come from a McKesson system and be sent through that network to some independent entity, if

that's what you decide.

The third way is to require pharmacies to load tracking software in their system that specifically scrape out, they detect patterns based upon unique algorithms that you all decide upon. You can say here's the algorithm that we want, here's what we want it to pull out, and you could pull out that information and report it to a third party. It can report it to a third party through the Internet, it could report it to a third party through a telecommunication line, or it can produce manual reports that you can send.

And the last way in which I am been sort of talking about today is that we're in the throws of building a statewide health information exchange that would support this kind of functionality. That system will not be ready for this sort of use case, and we'll just call it a use case. Prescription drug monitoring is something specific, so we'll call that a use case. It won't be ready to do that for three to five years. But if the group says this is a recommendation, then

the group that we select to build the infrastructure would be asked to take this as a use case at some point in time.

If you look at it from cost, there is going to be cost to every one of these. The first three there are costs to both end points. There is cost to the physician side and there is a cost to the pharmacy side. The last way there is a cost to the system, but not to the pharmacy or to the physician. It is a cost to the system.

JUDGE FADER: We're going to talk sometime in this group about grants to delay or keep under control the cost to the pharmacists and the cost to the physicians.

DR. SHARP: Sure.

JUDGE FADER: But one of the big ticket items on that screen is who is the third party who is going to get this information? And there are many members of this council who feel that there is going to have to be a marriage of sorts between physicians who know this field and the prosecuting authority to

say, this is not bad medicine, or this is bad medicine. Because we do not want that third party, a lot of us, going overboard in prosecuting either through the Board of Physicians or through the prosecutors without the benefit of advice of the medical people. Look, there is no way I can tell Pat Jessamy or Doug Gansler what to do. They are the elected officials, but many people here are -- those two words, third party, is very, very important, that Doug and Pat have the benefit of the advice of whatever this group is going to be, that you can go ahead and do this, but this is not that bad medicine. This is not bad medicine. I think we need to keep our eyes on that. And you should know that that's going to be one of the main considerations for all of us.

DR. SHARP: And I anticipated --

JUDGE FADER: People who don't go overboard without the benefit of advice of people when these things are called into question.

MS. KATZ: I would just add that we also want this, whatever it is, if we have anything at all,

to benefit the patient, to benefit the patient's health care to make sure to prevent errors, but also to be sure the patient continues to have good access and that the system would identify patients who may have a problem with addiction in particular, and identify them as patients, as opposed to something else.

DR. SHARP: I think your point, ma'am, and, Judge, your point sort of speaks to the things I kind of anticipated would come up. And that's really the policy questions, in part. There are others. Who owns the data, who controls the data, who should have access to the data, who is authorized to view the data, how are users of the data authenticated, and how long should the data be maintained. Once it gets to this third party, does it stay there indefinitely, does it disappear in six months or two years.

But that third party is that X factor that you all are sort of chewing on and figuring out how you want it to go. Because it is an important component to resolve. If there were an easy answer we

all probably wouldn't be here today. That's why it requires thought and perspectives.

MR. KOZLOWSKI: Let's talk about what you and I talked about earlier, and that is there are all kinds of capabilities to create edits in a system in which it would look for only specific situations that would be pulled out to potentially a subfile that the people you are concerned looking at it would ever have access to. There is tremendous control. I've done work with the National Bank of Canada, which is their Federal Reserve, and you know money moves electronically so you can anticipate a whole series of controls in there, who had access and what amount of information was going to go where. It is doable.

I think the important thing is to keep in mind that there are very, very sophisticated capabilities in this country moving our whole financial system. You use them all the time without much concern frequently, called ATMs. And it's become a world dependent on ATMs, and you can move money across the world. People sit by the cooler in the

office and talk about their medical problems. I have yet in all my many, many years, and there are a lot of them, ever heard anybody sitting at the cooler talking specifically about their financial situation. And yet we use ATMs without a question.

So there are controls in place and we need to step back and remember that. We live with them every day. But the most important thing, having run systems before, is that you can very much define who gets what, when, for what reason, and how. And David was very specific in showing you all the checks and balances that are in place. Is it a hundred percent perfect? There is no such thing. Anybody who can come up with that would be a billionaire. I literally had a team of hackers who worked at night to hack the system that my security folks put in place during the day. That's how we kept the system secure.

JUDGE FADER: Are all those people on parole? I'm only kidding.

MR. KOZLOWSKI: You are not really kidding because it took a long time to convince a governor to

allow me to hire hackers to hack a secure system in a secured environment so we really had a secure system.

JUDGE FADER: And that's something we need to keep in mind, too, that you convinced the governor to do this, which I did not know until right now.

MR. KOZLOWSKI: There is no question in my mind. I've done something recently with the Department of Defense and what they are using, and we know that's been hacked. There is not a perfect system, but it is really, really darn good. Because globally, folks, we move billions and billions of dollars a day without intervention worldwide. So that part we need to kind of calm ourselves about.

And then what he put up there is those indicators, that last slide. That's the important piece is sitting down and making the policy decision about who, where, when, and why, and for what reason.

DR. SHARP: Because in reality, this is what is going to close it up. The technology can be built. There are many different vendors. I think there are four or five out there today that nationally

do prescription monitoring programs that I've looked at. It is not so much the technology, it is your point, how is it used, how do you derive benefit of it, how is it safeguarded, how is it protected. In the end how does it make care better.

One last thought I would share with you -- and I think you did have one question so I wouldn't want to cut you off -- is that whatever you decide, if you try to make your decision based upon where the state is going, if the state is moving to an informational highway, if you decide on a unique stand-alone system, will it fit within that universe, or does it become another disparate system that requires physicians and pharmacists to maintain yet another system for cost, for maintenance, for programming. It becomes a financial burden to whoever is on the end points and it never really gets to helping the patient, physician, and the end point because it is disparate.

JUDGE FADER: David, one of the things that keeps coming up is for programs of this sort the

benefit of a multi-state system. One of the things we need to know about your system, a lot of the people that are down near the southern end of the state have the benefit a lot of times of getting together with West Virginia, Virginia, people of that sort. So what is going to be there with regard to the system that the state is going to have in three to five years? Are you looking to make that so that it is going to be compatible with other states, or other states are going to be able to inject compatibility in there or whatever?

And of course the DEA is very, very interested on the federal level as to how that's going to comport with their system, too, because they want to tap in on all this stuff also. All of those things are real questions that sometime along the line we're going to have to find out the answers to.

Bob, anything else on that line, or have I pretty much covered it?

DR. LYLES: From the point of view of going back a couple years, this originally came about

because of the Attorney General. It sent a chill through the medical community when that happened.

JUDGE FADER: Through Joe Curran?

DR. LYLES: Absolutely. He is going to come and talk.

JUDGE FADER: And he tells me, by the way, John, how can there be problems, I talked to everybody. I said, Joe, when you come to the meeting, you will find out where the problems are. He said okay.

DR. LYLES: We have in the past two to three years, the database industry has progressed substantially. And look at where you guys are and where you are going. The task force, this prescription drug monitoring, is not opiate monitoring per se. What we would like to have in the medical community is a better management tool. I don't want to know just the opiates. I want to know the benzodiazepines, I want to know the blood pressure pills, I want to know everything the patient is on so I can help manage that patient better. And I'd like

to have some transparency through the different physicians that they see.

What worries me about the original concept of this is something we now see on the television called sexing (sic.)

JUDGE FADER: Called what?

DR. LYLES: Sexing.

MS. KATZ: Sexting.

DR. LYLES: Instead of when you and I were growing up, a young lady would just pull up her dress and say look at this.

JUDGE FADER: Nice neighborhood.

DR. LYLES: Now it is on the cell phone and it goes across the network. And there is one kid on here that's been prosecuted for what do they call it, underaged sexual something. I don't know what these terms are.

JUDGE FADER: It is statutory rape or things of that sort?

DR. LYLES: Because they are under age, but you have got a fifteen year old transmitting the

pictures to a sixteen year old, and now you have problems because somebody wants to make political hay of it. This is what worries us about this.

Let me finish. We have had difficulties with insurance companies using this data surreptitiously. If a patient is on Lexapro and tries to get a private policy, all of a sudden the premiums go right through the ceiling. And that's just wrong.

JUDGE FADER: And that should not be. That absolutely should not be. And under Maryland and some other states they are not supposed to have access to that data. There are more states that allow them to have access to that data.

DR. LYLES: And now we're getting into pain management. We are getting into gene testing. Are you a fast metabolizer or slow metabolizer? What is overprescribing? We don't know what overprescribing is.

So this data is very important on a personal basis, not only employing it, but what is going to happen in the legal community with people. And we're

all captured in our boxes of past experiences. The attorneys see things one way. I see things another way. I get out in the community a little bit, I try to understand their side. They try to understand my side and so forth because we want to communicate. But how this data is used is the major problem that we have here.

DR. SHARP: And that's a good point. Let me just sort of touch here and here before I stop completely. The question about what happens when you have different systems and will the state be able to interact with other states. When you look at the vendors out there today and analyze their product, they are very disparate. These products won't interface with one another unless the nation appoints one vendor as the end-all for a prescription drug monitoring program because they won't communicate.

When you get across state boundaries, these health information exchanges that all states are moving in the direction of, they're following similar standards. There are some variations, but they're

following similar standards. So inevitably ten years from now there will be limited data exchange for cross state adverse events or just events in general. So if the patient is on the border of Maryland and goes to a Delaware hospital --

JUDGE FADER: So you see this much further away?

DR. SHARP: Absolutely. Within the state you are three to five years if you use the infrastructure of a health information exchange. You are faster if you use a defined vendor, but that defined vendor won't be able to communicate outside the borders because every vendor asks for different parameters and their software is not compatible with the next.

JUDGE FADER: I just want to reiterate my situation. The Constitution says that I can't interfere even as a judge with their decision to prosecute. But what I have to feel, we have got to come up with here is some sort of a system to give them advice whether they want it or not, and to make

their decisions to prosecute based upon that medical advice.

DR. LYLES: Just like the fifteen and sixteen year olds.

JUDGE FADER: Well, I understand all of your problems, but the Constitution is not going to allow any of us to interfere with the prosecutorial right of the Attorney General of the United States or the State's Attorney for Baltimore County or Baltimore City. That's just not going to happen because there is not going to be a constitutional change.

But the situation is that what we can hope for is a system that the prosecutors will join us in saying when they have problems that they will have the benefit of advice as to whether this is overprescribing or will take no position.

Ramsay, you sure have been outspoken about all of that.

DR. FARAH: I am very concerned because it is up to extort. Today there are communities in Pennsylvania that are bordering us in western Maryland

that I can tell you probably fifty percent of the residents of Saxton, Pennsylvania have access to prescription medication that is filtering to Maryland in a huge amount. I have treated four hundred patients. It is very, very worrisome because when you talk about access, and I'm sitting here thinking how am I going to get to know these doctors and get them the information they need to know to stop prescribing the stuff and stop the influx of these pills into Maryland. No matter how tight we are we have all these neighboring prescription systems.

And with the same breath I'm worried, we are reviewing cases all the time, you can't imagine how many cases we review where we have had complaints. This is overprescribing. I look at it, no. It is appropriate therapy. Why are we prosecuting this?

JUDGE FADER: What I see as an issue, when the DEA and prosecutors go down to the Legislature to give them the benefit of their advice with regard to all of this, and they will be going down there, I know, that they can keep all of this in mind as to the

concerns with all of this and the importance of injecting some medical opinions from good people into all this. You are all going to vote as to how you want all of this to come. But that's the way I see it, is there is going to be no interference with the prosecutorial function and I would hope that the prosecutors can join in on this to say that perhaps it is good to seek advice. But go ahead.

DR. LYLES: When you get into the legal aspects of this, you are presuming that we know what we are doing. We don't.

JUDGE FADER: Who is "we"?

DR. LYLES: Doctors, physicians, the medical community. You are prosecuting on the basis of something called standard of care. Is it the right medicine or not? This is an ever evolving system.

And you and I have talked about it, standard of care. It changes monthly. Two years ago we didn't have any idea about testing, genetic testing for a fast metabolism versus a slow metabolism. Five years ago I didn't think I would ever do stem cell implants

in the office. We do now. This is ever evolving.

JUDGE FADER: But there are certain things that you know are way overboard. There are certain things with regard to this pain medication that Ramsay knows that are way overboard. They just are not good medical practice.

DR. LYLES: We don't know that. No, no, no, you don't know that.

JUDGE FADER: In certain cases you can identify that.

DR. LYLES: You don't know because I don't know that, and I'm the expert. I'll have a colleague who will come here and he may say, yeah, we have got overprescribing, but we can't define overprescribing, you can't define it with the Board. You can have an idea.

DR. FARAH: Just to give you a thumb nail sketch what we have been doing. When we have a complaint, we look at the medical records, we look at the pattern of that physician, we look at documentation. We do a practice review, and we have

peers that look into that and give us reports. And we analyze it very thoroughly, and I can feel very comfortable that a lot of the physicians we have disciplined -- and I can tell you we have disciplined a whole bunch of physicians -- and the reason why is because you can see a consistent pattern of inappropriate management, on, and on, and on. And I don't -- I can sleep very well at night knowing that we yanked the license of these physicians.

JUDGE FADER: Some of it is for overprescribing?

DR. FARAH: That is correct. On the other hand, there have been specific cases where we have very, very, very thoroughly argued that this has not been improper care, these circumstances are such that this patient did require this massive dose, this high combination. So part of this whole thing is going to be a tremendous amount of education and documentation, and trying to make sure colleagues recognize the importance of this and properly put to paper the data that supports the approach of why they handled what

they handled.

DR. LYLES: You did talk about documentation, and in many cases what you are prosecuting on is improper documentation rather than medical judgment. I read many of these things.

DR. FARAH: Let's face it. The police officer goes into that doctor's office and in his office there are about 125 different bottles written to ten different patients of huge amounts of medications. You open up the drawers and there is --

DR. LYLES: These are the egregious, I understand that.

DR. FARAH: The patient is allowed to come in and say what do you want today. Some of it is so flagrant it doesn't take anybody to know. These are the bad acting individuals.

DR. LYLES: And we do have a minority of them, I understand that.

JUDGE FADER: We're going to call upon the prosecutors at some point, not these two, but after they confer and we are going to look at other states

as to what they have done with regard to this. And this is one of the key issues that we're going to have to come up with. There is prosecutorial authority is what it is, constitutional. The situation is how are we going to handle these questions that are exchanged and I know you want to weigh in on this, too. And I don't know the answer to that.

DR. COHEN: One point pertaining to this overprescription, and then another point, and then a question. And I like making things brief.

First, from our perspective, I get reports from people who have died from methadone overdoses, and there is a new methadone overdose, a methadone mortality report that's out. It is not coming from methadone maintenance programs, but these deaths are coming from other places. The ones that concern me are the people who are severely mentally ill and the number of reports that they die from methadone overdose. They get it some other way, and the kind of training that is necessary is really important.

Which comes next to data. We have in

electronic medical records called Smart. And if you take a look at two methadone programs, you have one that is horrible and one that is good. And you say, let's bag the program. This is where you can't have prosecutorial push because you are going to see that this program is in a very poor area where people tend to be inconsistent without the social security. They are handling tough people, so you can't compare the two with the terms of what the outcome and one is doing a poor job and one is giving out too much methadone for example. You have to be very, very careful.

Now, to get to in terms of electronic data, we have a system where we're going to have people e-prescribing and hopefully we have a module. What I'm learning out of this is if we only have six percent of physicians doing this, you start to get, let's say, a hundred percent, what a mess in terms of the amount of data coming through, which now we have nonstandardized transactions, you are now having to translate and then make it standardized so it can be

interpreted.

DR. SHARP: The networks do that today anyway for all kinds of data, in a nanosecond.

DR. COHEN: My question is, is it going to get jammed up?

DR. SHARP: No, no.

DR. COHEN: Are you going to have to have more equipment, purchase more equipment to handle all of that, which also costs.

DR. SHARP: Not at the end points. It happens in the middle, the intermediary, the vendors, the infrastructures in the middle will expand. The end points won't. The upgrades, but the end points is small.

DR. COHEN: We are talking about something that is for the public good and you are speaking about the necessity for standardized transactions.

DR. SHARP: I stayed away a little bit from the whole public utility piece because I thought it would take us too far in another direction. But there is a tremendous amount of public good that comes from

a utility like this.

DR. COHEN: I will urge, and I know I'm not a member of the council, but I would urge a discussion about the necessity for certain standards. We are not talking about the difference between Blu-ray and High Definition or Beta versus VHS. We are talking about a public good that costs a certain amount of money. And you have to have standards. It is a difference of concensus and market driven, you have to have leadership, make a decision on the public good. We can't afford --

DR. SHARP: No question. The infrastructure for the states that are moving into health information exchange, there is an entire component that refers to the public good. It is secondary uses of data, whether research or biomedical purposes, whether it be for adverse events. There are just tons of opportunities that we can talk a great bit about, and the research out there is just enormous. On the secondary because uses of protected health information, pharmacy data, medical data -- it is

claim data, but it is there. Good question.

JUDGE FADER: David, I thank you very much. We all thank you very much. We have certainly had a resurrection today of the different problems that we see we're going to just have to deal with.

I again would ask here if -- I'm going to ask Georgette just to send out an e-mail. I'm interested in this July 3rd or 10th. Does anybody have any real preferences? The 3rd is kind of close to the 4th of July.

MS. KATZ: You said the 10th or the 17th.

JUDGE FADER: What did I say, the 10th or the 17th? Okay.

DR. LYLES: 17th is best.

MR. KOZLOWSKI: That's fine.

DR. COHEN: 17th.

JUDGE FADER: All right. Georgette, I would also like you to send out an e-mail saying that the tentative meetings for September are September 10th, for October are October 9th, November are November 13th. That's the second Friday. Anybody have any

objection, as opposed to the first Friday? And that these are pretty much going to be the work sessions. Because following this June 3rd meeting, you are going to get -- after Georgette, Michael, and I sit down, you are going to get an e-mail from us saying here are the issues, who wants to add to it, who wants to subtract from it, who wants to rearrange it, categories and things of that sort. And that will be the primary discussion at -- what did we say, July 10th or the 17th -- the 17th meeting, then, to have all of the issues and the different statutes available as we come to these meetings, and ideas as to how people will handle all of this. Anybody have any comments on that, questions about it, anything of that sort?

MS. HERMAN: It is September 11th.

JUDGE FADER: That's a Friday. Is it the 11th? Well, Georgette knows to check everything I say by now, don't you? Anybody have any other comments? Anybody have any discussions, anything else? Well, our law enforcement people, take back to the powers

that be the resurrected concern of what is going to happen here as far as all of this.

MS. FORREST: Sure. I think just to keep in mind, like Agent Sponheimer said, we're not intending to do any kind of fishing expedition. We are only here to do what has been violated. Just like Dr. Farah has done things that's based on information of great concern, that you aren't seeking out these doctors. And that's the same as law enforcement. Prosecutors don't get involved until law enforcement has officially done an investigation and saying these are all the violations, whatever safeguards or programs have been in place, whatever laws have been violated. We have plenty of work to do not to go on fishing expeditions to try to find doctors. Just like you find doctors that are violating things, that's how we'll also be involved.

JUDGE FADER: But, LaRai, everybody is talking about the third party who has access to this data, and that third party is not going to be a single individual. It is going to be a group of people, and

the big question is who is that going to be because that party -- I think the sense of this group is they want to be able to make recommendations to the prosecutors.

DR. FARAH: Do we want a bunch of technocrats to look at the data and say, you know what, there is a potential problem, it is worth doing X, Y, and Z, or you know what, let's start right now and get the SOB or whatever.

JUDGE FADER: We really want input from the prosecutors as to who this third party is, what is acceptable there, on a recommendation basis, so when we go down to the Legislature and make a recommendation and they start asking questions about this, it certainly would be a lot better if all of us can get together on an acceptable type of thing with a majority vote, minority vote, and things of that sort. Did anybody have any comment on that right now?

MR. RILEY: Just to support what LaRai is saying, we have got about six investigators looking at

the entire state. As this gentlemen said, we're looking at registrants who are off the chart. These are people that are doing undercover deals, operating outside their practice, that are just so flagrant and they are already on the radar screen. It is not something where we're proactively looking for targets. We just don't have the time.

JUDGE FADER: I don't see the DEA much in Baltimore County unless somebody is running around with thirty or forty pounds of something in the back of the trunk.

DR. LYLES: That's been our experience, too, working with you guys.

JUDGE FADER: But I do see the Attorney General's Office is going to want to have something to say about this, Pat's office, and people like that. Anybody else have any comments, questions?

Who our visitors are today, you need to sign in, and you need to tell Georgette whether you want a copy of this transcript, too. So you are entitled to all of that, and the reason you are entitled to it is

because you are Maryland citizens. And so we'll send you copies of everything. Did everybody get a copy of the last transcript? Anybody who wants it who hasn't gotten it?

(Discussion off the record.)

JUDGE FADER: Again, June 3rd -- 5th rather. And, Gail, we need to get together with you, and does anybody else wants to be in on this meeting that Georgette, and I, and Michael will have with Gwenn and Gail? You are welcome to it. Anybody want to be notified of the date? We'll meet preliminarily. We met with David. Anybody else? Okay, well, if anybody does, we'll put a note out. Ann. Ann wants to come to all the meetings, God bless her.

I will e-mail both of you and I will suggest a breakfast meeting someplace. You work here?

MS. KATZ: I live in the City. We'll come someplace on the lower end, probably Columbia or the airport. We had a nice meeting the other day at the airport where you don't have to come through Baltimore

City 7:30 in the morning.

JUDGE FADER: What time? Gwenn, around 10, is that okay?

MS. KATZ: Not for breakfast.

MS. HERMAN: I can't wake up that early.

JUDGE FADER: Let me e-mail all of you and tell you. Most of the rest of us are.

David Sharp, I have seen your lectures many times. They're excellent. They're to the point. And we thank you very much.

DR. SHARP: My pleasure.

JUDGE FADER: We'll be calling upon you, and thank you very much for everything.

DR. SHARP: You bet.

JUDGE FADER: June 5th.

MS. KATZ: Was this an easy location for most people?

JUDGE FADER: Is there somebody else who has a -- Kaiser Permanente. Where is Kaiser's representative? And where is your location?

MR. FRIEDMAN: I don't know the exact

address, but it is Columbia Gateway.

JUDGE FADER: Same place as before.

MR. FRIEDMAN: It is very close.

DR. FARAH: For me it is a forty minute less drive. If nobody has any objections, Columbia is on the south side and you don't have to go through the City.

JUDGE FADER: We'll have it there the next time, and would you be in contact? Thank you.

(Whereupon, the meeting was adjourned at 11:45 a.m.)